UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,900	02/23/2004	Nelson Scarborough	00167-492001 / 02-31-0466	5935

7590 02/12/2007

Joel R. Petrow, Esq.
Chief Patent Counsel
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116

EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,900	SCARBOROUGH ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-18 and 37-58* is/are pending in the application.

4a) Of the above claim(s) *42-43, 51, 53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-18, 37, 41, 44-47, 55-58* is/are rejected.

7)☒ Claim(s) *38-40,48-50,52 and 54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 11/28/2006.

2. In the reply fled on 9/11/2006, the Applicant added new claims with required a new election/restriction requirement to be made. Additionally, in the reply filed on 9/11/2006, the Applicant cancelled claims 1-7, 19-36, amended claim 8 and 12, and submitted replacement formal drawing sheets.

Election/Restrictions

3. Claims 42-43, 51 and 53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/28/2006.

4. Claims 8-18, 37-41, 44-50, 52, and 54-58 remain pending for examination.

Claim Objections

5. Claim 46 is objected to because of the following informalities: Claim 46 recites the limitation "a response of the patient input directly by the patient" in ln 7, the Examiner believes the correct claim limitation should read a response of the patient *inputted* directly by the patient. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the limitation "response data indicative of magnitude and quality of a response". The limitation "magnitude and quality of a response" fails to particularly point out and distinctly claim the subject matter because the terms have no meaning in relation to the response. What defines the magnitude and quality of a response of the patient? The interpretation of the limitation is subjective and unclear because a magnitude and quality of a response could literally be almost anything and could be defined in a subjective manner in a variety of ways.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 8-18, 41, 44, and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Duchon et al (2003/0028144).

10. In reference to independent claim 8, Duchon et al discloses a fluid introduction system, comprising: an introducer (18; Fig 1); an operator (12); a computer readable medium having code for receiving: fluid introduction data indicative of a fluid introduction parameter ([0018]); and response data indicative of a magnitude and quality of a response of the patient at a time related to a time of the fluid introduction data ([0021]).

The Examiner further notes that while the injection system of Duchon et al is silent on whether the injection system can be used in the spine the injection system is Duchon et al is fully capable of being used in the spine. Further evidenced is provided by the injection system's ability to inject at pressures up to about 1200 psi [0084] a pressure value far above the applicant's minimum desired 69 kPa (approx. 10 psi) or 100 kPa (approx 14.5 psi).

11. In reference to claim 9, Duchon et al additionally discloses wherein the fluid introduction parameter is a pressure within an intervertebral disc of the patient at the time of the fluid introduction data ([0020]).

12. In reference to claim 10, Duchon et al additionally discloses wherein the fluid introduction parameter is a total amount of fluid introduced into an intervertebral disc of the patient at the time of the fluid introduction data ([0020]).

13. In reference to claim 11, Duchon et al additionally discloses wherein the fluid introduction system is configured to obtain the response data upon an observation by the patient ([0020], [0021]).

14. In reference to claim 12, Duchon et al additionally discloses wherein the fluid introduction system is configured to obtain the response data upon a response input by the patient ([0020], [0021]; and discussion in Response to Arguments; the Examiner further notes that any observation or reading taken from a patient and sent to the controller can be said to be inputted directly from the patient because the data response originates at the patient and is then inputted directly into a controller). The Examiner suggests adding the term manually inputted to further clarify the Applicant's invention.

15. In reference to independent claim 14, Duchon et al discloses an introducer (18; Fig 1) configured to introduce a non-pulsatile flow of fluid into a spine, the introducer having a flow rate-dependent impedance (104) opposing the introduction of the fluid; and an operator (12) configured to actuate the introducer, the operator including code [100] to control the actuation of the introducer based at least in part upon impedance data indicative of the impedance ([0121]).

16. In reference to claim 15, Duchon et al additionally discloses wherein the introducer includes an identifier (114) including the impedance data and the operator is configured to receive the impedance data from the identifier of the introducer ([0121]).

17. In reference to claim 16, Duchon et al additionally discloses wherein the operator includes code to determine the impedance data based upon an actuation of the introducer ([0120]).

18. In reference to claim 17, Duchon et al additionally discloses a pressure sensor (114) configured to provide pressure data indicative of a pressure of fluid present in the introducer ([0121]); a fluid introduction sensor (108, 110, [0120]) configured to provide fluid introduction data indicative of at least one of (a) a rate of fluid introduction and (b) an amount of fluid introduced ([0120); and wherein the operator includes code to determine the impedance data based upon the pressure data and the fluid introduction data ([0120]).

19. In reference to claim 13 and 18, Duchon et al additionally discloses wherein the introducer is configured to create a pressure of at least 69 or 100 kPa within the spine (0005], [0084]).

20. The Examiner further directs the Applicant to the Summary of the Invention ([0012]-[0022]) and the Specification ([0155]-[0185]) for a further discussion of the functioning of the operator of Duchon et al.

21. In reference to claim 41, Duchon et al additionally discloses wherein the response data comprises observed physiological parameters ([0020]-[0021]).

22. In reference to claim 44, Duchon et al additionally disclose wherein the response data is correlated with actual measurements of disc pressure and a volume of fluid introduced into one or more discs ([0020]-[0021]; wherein the Examiner notes that the device of Duchon et al is fully capable of correlating the response data (a patient physiological value) with actual measurements of disc pressure (pressure of injection fluid into the body, which is fully capable of being a patient's disc) and a volume of fluid introduced (volume of medical fluid injection).

23. In reference to claim 45, Duchon et al additionally discloses wherein the needle is fully capable for being configured for insertion into a spine (see above arguments in regards to claim 8).

24. In reference to claim 46, Duchon et al additionally discloses the invention substantially as claimed (see claim 12, and Response to Arguments below).

25. In reference to claim 47, see discussion of claim 44.

26. Claims 14-17 and 55-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Hochman et al (6945954). Hochman et al discloses a fluid introduction system, comprising: an introducer (Fig 1) configured to introduce a non-pulsatile flow of

fluid into a spine, the introducer having a flow rate-dependent impedance opposing the introduction of the fluid (Summary); and an operator (18) configured to actuate the introducer, the operator including code to control the actuation of the introducer based at least in part upon impedance data indicative of the impedance (col 3, lns 11-col 4, lns 54); wherein the introducer includes an identifier (col 7, lns 10-13; 208) including the impedance data and the operator is configured to receive the impedance data from the identifier of the introducer; wherein the operator includes code to determine the impedance data based upon an actuation of the introducer (col 3, lns 11-col 4, lns 54; Program Listing); further comprising: a pressure sensor (7) configured to provide pressure data indicative of a pressure of fluid present in the introducer; a fluid introduction sensor (208) configured to provide fluid introduction data indicative of at least one of (a) a rate of fluid introduction and (b) an mount of fluid introduced into the portion of the spine (col 3, lns 11-col 4, lns 54); wherein the operator includes code to determine the impedance data based upon the pressure data and the fluid introduction data (col 3, lns 11-col 4, lns 54, Program Listing); wherein the impedance data comprises a gauge of a fluid introduction member, a length of a fluid introduction member, an inner diameter of a fluid conduit; and a length of a fluid conduit (col 3, lns 11-col 4, lns 54; Program Listing; col 7, lns 10-13; col 9, lns 29-49).

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

28. Claims 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duchon et al in view of Prais et al (2001/0039402). Duchon et al discloses the invention substantially as claimed except for expressly disclosing the response data comprises a patient's paint level and concordance. Prais et al teaches that it is known to have the response data comprises a patient's paint level and concordance ([0035]) for the purpose of assessing the injection with respect to pain, sharpness, and general feeling of the injection. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the response data as taught by Duchon et al to additionally include the response data as taught by Prais et al for the purpose of assessing the injection with respect to pain, sharpness, and general feeling of the injection.

Response to Arguments

29. Applicant's arguments filed 9/11/2006 have been fully considered but they are not persuasive.

30. The Applicant argues that Duchon et al does not teach or suggest:

i. Computer readable medium having code for receiving response data indicative of magnitude and quality of a response of a patient at a time related to a time of fluid introduction data and that measured heart rate is not indicative of a magnitude and quality of a response of a patient.

31. In response to the Applicant arguments (i), the Examiner strongly disagrees with the Applicant's characterization of what is indicative of a magnitude and quality of a response of a patient. A measured and received response data, described in [0021], is clearly recorded at a time related to a time of fluid introduction data. Furthermore, "a response of a patient" is a very broad limitation and the Examiner notes that measuring a patient's heart rate, blood pressure, and ECG signal (see [0107]-[0110]) all can clearly constitute a response of a patient to at a time related to a time of the fluid introduction data because they can change over time in relation to fluid introduction into the body. The rejection is maintained.

ii. The fluid introduction system is configured to obtain the response data from an observation of the patient.

32. In response to the Applicant arguments (ii), the Examiner notes that observation of the patient clearly includes measuring, or observing, a patient's heart rate, blood pressure, and ECG signal (see [0107]-[0110]).

iii. The claimed operator including code to control the actuation of an introducer, which has a flow-rate dependent impedance opposing the introduction of fluid, based at least in part upon impedance data indicative of the impedance and and introducer which includes an indentifier including the impedance data and the operator is configured to receiving the impedance data from the identifier.

33. In response to the Applicant arguments (iii), the Examiner notes that the Applicant ignores the Examiner's previous citations and cites their own citations. The

Examiner again directs the Applicant towards (18, Fig 1; (104); (12), (100); [0100]; and [0121]) wherein Duchon et al describes how the operator (12, 100) controls the actuation of an introducer (18, Fig 1, and 104), which has a flow-rate dependent impedance opposing the introduction of fluid (the amount of impedance occurring in the introducer opposing the introduction of pumped fluid by the motor into the body) based at least in part upon impedance data indicative of the impedance ([100], [121], and (114); wherein the pressure sensor is the identifier that senses the impedance and sends it to the operator to control the motor to control actuation of the introducer bases upon flow-rate dependent impedance. Thus, the rejection is maintained.

Allowable Subject Matter

34. Claims 38-40, 48-50, 52, 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

35. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert